REMARKS

Reconsideration of the rejections is respectfully requested.

The status of the claims is as follows:

Amended:	27, 34, 53
Cancelled:	54
New	62-64
Pending:	27-29, 31, 34-35, 53, 62-64

The claim fee status is as follows:

☒ Large Entity
☐ Small Entity

		After Amdmt	Paid for	Fee due for	Fee code
	Independent Claims:	1	5		Lg =102 Sm =202
	Total Claims	10	35	0	Lg =103 Sm =203

The number of total claims and of independent claims remains less than the amount for which fees were previously paid.

The claims have been amended to more clearly define the invention. Support for the amendments is either apparent, or is as described below. Support for new claims 62-64 can be found, for example at page 70, lines 4-11. No new matter is added.

Claim Rejections - 35 U.S.C. §112, First Paragraph

Claims 27, 53 and 54 stood rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention. In particular, the Examiner alleges that the specification does not provide enablement for a vaccine composition.

Without conceding the correctness of the rejection, Applicant has elected to present the invention in different terms, which terms obviate the rejection. Reconsideration, and withdrawal of the rejection under §112, first paragraph is respectfully requested.

Claim Rejections - 35 U.S.C. §112, Second Paragraph

Claims 27-31, 34, 35 and 53-54 stood rejected under 35 U.S.C. §112, second paragraph, based on an assertion that certain terms in the claim rendered the claims insufficient to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. In particular, the Examiner requested clarification of the term "T-cell immune response" clarification of the T-cell mediated response is directed to in claim 27.

Reconsideration is respectfully requested. Applicant has amended claim 27 to more particularly and distinctly define the subject matter of his invention. In addition, Applicant submits that the specification clearly and adequately provides for the meaning of the terms T-cell mediated immune response For example, the specification provides that cellular immunity arises from CTL or CD4+ T-cells (see, for example, page 34, lines 8-10).

The Examiner also objected to the terms "one other M. catarrhalis antigen" in claim 54.

Without conceding the correctness of the rejection, solely to expedite prosecution, Applicant has cancelled claim 54. Reconsideration of the rejection is respectfully requested.

Claim Rejections - 35 U.S.C. §102

A. Claims 27-29, 31 and 34 stood rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Helminen et al. (*J. Infec. Dis.*, 170, pp. 804-809, 1994). The reference was cited for disclosing outer membrane protein from Moraxella catarrhalis, and the Examiner posits that the whole cell lysates inherently comprise the amino acid sequence of SEQ ID NO:2.

Applicant respectfully disagrees. A claim is anticipated only if each and every element is found, either expressly or inherently described, in the reference. *See* MPEP 2131. Moreover, the identical invention must be shown in as complete detail as is contained in the claim. Applicant submits that Helminen et al. does not identically disclose Applicant's isolated polypeptide.

Abiding by these standards, Helminen et al. does not anticipate the invention as presently claimed. Accordingly, reconsideration of the rejection is respectfully requested.

Moreover it is submitted that the UspA1 peptide disclosed in Helminen et al. is not very similar to the claimed BASB019 proteins (see Exhibit C).

B. Claims 27-29 and 31 stood rejected under 35 U.S.C. §102(b) as being anticipated by Legace et al. (WO 0078968). In particular, the Examiner noted that Legace et al. disclose a polypeptide that is 100% identical to SEQ ID NO:2.

Applicants submit that the submission of the correct, concurrently filed amino acid sequence listings for the instant application (see above) obviate this rejection. Reconsideration of the rejection is respectfully requested.

FEE DEFICIENCY

☒ If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 50-0258.

and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 50-0258.

Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

E. A. Meade

Eric A. Meade
Registration No. 42,876
for
Allen Bloom
Registration No. 29,135
Attorney for Applicant

DECHERT LLP
1717 Arch Street
4000 Bell Atlantic Tower
Philadelphia, PA 19103-2793
Fax: (609) 620-3259
Attn: Eric A. Meade
(609-620-3248)

APPENDIX A: VERSION WITH MARKINGS TO SHOW CHANGES MADE

27. (Twice Amended) An isolated polypeptide comprising a member selected from the group consisting of

(a) ~~an amino acid sequence matching~~ SEQ ID NO:2~~, SEQ ID NO:4, SEQ ID NO:6, or SEQ ID NO:8~~;

(b) an immunogenic ~~polypeptide comprising a~~ fragment of SEQ ID NO:2, wherein the immunogenic fragment comprises ~~sequence of~~ at least 15 amino acids ~~that matches an aligned contiguous segment of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, or SEQ ID NO:8~~;

wherein the isolated polypeptide, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell immune response to a polypeptide consisting of ~~having the sequence of~~ SEQ ID NO:2~~, SEQ ID NO:4, SEQ ID NO:6, or SEQ ID NO:8.;~~

34. (Twice Amended) The isolated polypeptide of claim 27, wherein the isolated polypeptide consists of SEQ ID NO:2~~, SEQ ID NO:4, SEQ ID NO:6, or SEQ ID NO:8~~.

53. (Once Amended) An immunogenic composition ~~A vaccine~~ comprising the polypeptide of Claim 27 and a pharmaceutically acceptable carrier.

BESTFIT of: basb019.pep check: 7443 from: 1 to: 172

to: uspa1_o54356.pep check: 5128 from: 1 to: 832

Symbol comparison table: /home/junon/gcg/gcgcore/data/rundata/blosum62.cmp
CompCheck: 1102

Gap Weight:	8	Average Match:	2.778
Length Weight:	2	Average Mismatch:	-2.248
Quality:	39	Length:	59
Ratio:	0.722	Gaps:	2
Percent Similarity:	35.849	Percent Identity:	28.302

Match display thresholds for the alignment(s):
| = IDENTITY
: = 2
. = 1

basb019.pep x uspa1_o54356.pep January 17, 2003 10:24 ..

```
                .         .         .         .         .
    104 VAGHTDERGSREYNMSLGERRAVAVRNY.LLGKGINQASVEIISFGEERP 152
        : | ..   . ||.  .|     |   |  :| | |  .      ||
    120 IGGGSNNEATNEYSTIVGGDDNKATGRYSTIGGGDNNTAE.....GEYST 164

    153 IAFGTNEEA 161
        :| | | :|
    165 VAGGKNNQA 173
```

NiceProt View of TrEMBL: O54356

General information about the entry

Entry name	**O54356**
Primary accession number	**O54356**
Secondary accession numbers	None
Entered in TrEMBL in	Release 06, June 1998
Sequence was last modified in	Release 15, October 2000
Annotations were last modified in	Release 23, February 2003

Name and origin of the protein

Protein name	**High molecular weight outer membrane protein**
Synonyms	None
Gene name	**USPA1**
From	Moraxella catarrhalis [TaxID: 480
Taxonomy	Bacteria; Proteobacteria; gamma subdivision; Moraxellaceae; Moraxella.

References

[1] SEQUENCE FROM NUCLEIC ACID.
STRAIN=O35E;
MEDLINE=98013056; PubMed=9353007;
Aebi C., Maciver I., Latimer J.L., Cope L.D., Stevens M.K., Thomas S.E., McCracken G.H. Jr., Hansen E.J.;
"A protective epitope of Moraxella catarrhalis is encoded by two different genes.";
Infect. Immun. 65:4367-4377(1997).

[2] SEQUENCE FROM NUCLEIC ACID.
STRAIN=O35E;
Hansen E.J.;
Submitted (JUN-2000) to the EMBL/GenBank/DDBJ databases.

Comments

None

Cross-references

EMBL	U57551; AAB96359.2; -.
InterPro	IPR000515; BPD_transp. IPR000719; Prot_kinase. IPR005594; YadA.
Pfam	PF03895; YadA; 1.
PROSITE	PS00402; BPD_TRANSP_INN_MEMBR; 1. PS00107; PROTEIN_KINASE_ATP; 1.
Implicit links to	ProDom; ProtoMap; PRESAGE; ModBase; SWISS-2DPAGE.

Keywords

None

Features

None

Sequence information

Length: **832 AA**
Molecular weight: **88292 Da**
CRC64: **5C47F4F273350F4B** [This is a checksum on the sequence]

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        10         20         30         40         50         60
         |          |          |          |          |          |
MNKIYKVKKN AAGHLVACSE FAKGHTKKAV LGSLLIVGAL GMATTASAQA TNSKGTGAHI

        70         80         90        100        110        120
         |          |          |          |          |          |
GVNNNNEAPG DYSFIGSGGY NKAEGRYSAI GGGLFNKATN EYSTIVGGGY NKAEGRYSTI

       130        140        150        160        170        180
         |          |          |          |          |          |
GGGSNNEATN EYSTIVGGDD NKATGRYSTI GGGDNNTAEG EYSTVAGGKN NQATGTGSFA

       190        200        210        220        230        240
         |          |          |          |          |          |
AGVENQANAE NAVAVGKKNI IEGENSVAIG SENTVKTEHK NVFILGSGTT GVTSNSVLLG

       250        260        270        280        290        300
         |          |          |          |          |          |
NETAGKQATT VKNAEVGGLS LTGFAGESKA ENGVVSVGSE GGERQIVNVG AGQISDTSTD

       310        320        330        340        350        360
         |          |          |          |          |          |
AVNGSQLHAL ATVVDDNQYD IVNNRADILN NQDDIKDLQK EVKGLDNEVG ELSRDINSLH

       370        380        390        400        410        420
         |          |          |          |          |          |
DVTDNQQDDI KELKRGVKEL DNEVGVLSRD INSLHDDVAD NQDDIAKNKA DIKGLNKEVK

       430        440        450        460        470        480
         |          |          |          |          |          |
ELDKEVGVLS RDIGSLHDDV ATNQADIAKN QADIKTLENN VEEELLNLSG RLLDQKADID

       490        500        510        520        530        540
         |          |          |          |          |          |
NNINNIYELA QQQDQHSSDI KTLKNNVEEG LLDLSGRLID QKADIAKNQA DIAQNQTDIQ

       550        560        570        580        590        600
         |          |          |          |          |          |
DLAAYNELQD QYAQKQTEAI DALNKASSEN TQNIAKNQAD IANNINNIYE LAQQQDQHSS

       610        620        630        640        650        660
         |          |          |          |          |          |
DIKTLAKVSA ANTDRIAKNK AEADASFETL TKNQNTLIEQ GEALVEQNKA INQELEGFAA
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       670         680         690         700         710         720
         |           |           |           |           |           |
HADIQDKQIL QNQADITTNK TAIEQNINRT VANGFEIEKN KAGIATNKQE LILQNDRLNR

       730         740         750         760         770         780
         |           |           |           |           |           |
INETNNRQDQ KIDQLGYALK EQGQHFNNRI SAVERQTAGG IANAIAIATL PSPSRAGEHH

       790         800         810         820         830
         |           |           |           |           |
VLFGSGYHNG QAAVSLGAAG LSDTGKSTYK IGLSWSDAGG LSGGVGGSYR WK
```